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| Division: Pharmacy Policy  | <b>Subject: Prior Authorization Criteria</b>   |
| Original Development Date:<br>Original Effective Date:<br>Revision Date: | February 9, 2016<br>February 24, 2016; January 21, 2022; June 16, 2022, January 9, 2023, May 11, 2023, January 24, 2024, May 8, 2024 |

**Testosterone (non-injectable formulations)**

**TOPICAL:**

- Clinical PA required (preferred): Androderm® patch, Testim® gel tube, Testosterone gel packet (Vogelxo), Testosterone gel pump (AndroGel®)
- Clinical PA required (non-Preferred): AndroGel® pump, Fortesta® gel pump, Natesto® nasal gel pump, Testosterone gel packet/tubes, Testosterone Pump (Axiron®), Testosterone topical solution, Vogelxo® gel packet/pump/tube

**IMPLANT:**

- Preferred: N/A
- Non-Preferred: Testopel®

**ORAL:**

- Preferred: **Jatenzo®**
- Non-Preferred: Kyzatrex®, Tlando®

**LENGTH OF AUTHORIZATION:** One year

**INITIAL REVIEW CRITERIA:**

- Patient is ≥ 18 years old; AND
- Patient is male; AND
- Patient has a diagnosis of primary or secondary hypogonadism;\* AND
- Patient does not have a history of prostate carcinoma or male breast carcinoma; AND
- Prescriber has submitted the results of two separate serum testosterone levels, each drawn in the morning, which indicate a low serum testosterone (normal range: 300 to 1,000 ng/dL) within the last six months.
- **For Jatenzo, patient must have trial and failure of an injectable testosterone preparation within the past year.**

\* Causes of hypogonadism are classified as primary which are due to failure of the testes, or secondary, which are due to failure of the hypothalamus or pituitary gland. Either type of hypogonadism, may be caused by an inherited (congenital) or acquired factor.

\* Examples of primary male hypogonadism include but are not limited to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchidectomy, chemotherapy, radiation therapy, toxic damage from alcohol or heavy metals, testicular infections (such as mumps) and chromosomal abnormalities such as Klinefelter’s Syndrome

\* Examples of secondary male hypogonadism include but are not limited to idiopathic gonadotropin releasing hormone releasing hormone (LHRH) deficiency and pituitary hypothalamic injury from tumors, trauma, or radiation.

\*\* Safety and efficacy in men “age-related hypogonadism” has not been established.

**PATIENTS WHO MEET CRITERIA SHOULD BE APPROVED FOR THE PREFERRED AGENTS**

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**CONTINUATION OF THERAPY CRITERIA:**

- Patient has been compliant with treatment based on refill history.
- Prescriber submits labs within the last twelve months indicating patient has a normal serum testosterone level on therapy (normal range: 300-1,000 ng/dL)

**DOSING & ADMINISTRATION:**

- Refer to product labeling at <https://www.accessdata.fda.gov/scripts/cder/daf/>